DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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October 12, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-101

Greg S. Wenbourne, President
Circle Sea Seafoods Ltd.
17361 Tye Street SE
Monroe, Washington 98272

WARNING LETTER

Dear Mr. Wenbourne:

We inspected your firm located at 17361 Tye Street SE, Snohomish, Washington, on March 6, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations cause your smoked salmon and pickled herring products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must implement the monitoring procedures listed in your HACCP plan (and smoking specifications referenced in your plan), to comply with 21 CFR 123.6(b). Your firm did not follow the monitoring procedure of checking smoke chamber, exposure time, and product internal temperature during the smoking operations at the hot and cold smoking critical control point. Monitoring of appropriate critical limits listed in the "smoking specs" are needed to control the food safety hazard of pathogen growth (*C. botulinum*), since your smoking specifications vary between product forms.

2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(C) (3). Your firm's HACCP plan for hot smoked salmon lists a critical limit, taking an internal temperature of the product at the completion of the smoking process, at the smoking critical control point that is not adequate to control pathogen growth (C. botulinum). The critical limit does not include the time of exposure of the product to the internal temperature listed in the "smoking specs" (i.e. [redacted]°F)."

3. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(c)(1). Your firm's HACCP plan for pickled herring does not list the food safety hazard of pathogen growth.

The above violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA, including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating. Pertinent sections of the Act and regulations are enclosed for your review.

For your information, our investigator also noted during the inspection that your HACCP plan did not list the critical control of label review for controlling the food safety hazard of allergens (soy, Yellow #6, Red #40) in your smoked salmon products. Our Center for Food Safety and Applied Nutrition (CFSAN) and Office of Seafoods is currently in the process of clarifying their position on this issue and a formal policy has not been issued.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement